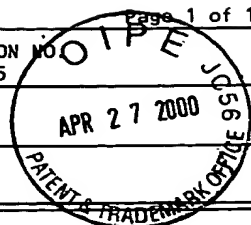


FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1887.0020001/RWE/KKVAPPLICATION NO.
09/430,175APPLICANT
LESKO *et al.*FILING DATE
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1648

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
KAC	AA1	5,529,903	06/25/1996	Kübler <i>et al.</i>	435	7.23	08/25/1993
KAC	AB1	5,962,237	10/05/1999	Ts'o <i>et al.</i>	435	7.23	04/02/1997
KAC	AC1	6,025,128	02/15/2000	Veltri <i>et al.</i>	435	6	09/29/1994
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	1	Afify, A. and Mark, H.F.L., "Fluorescence In Situ Hybridization Assessment of Chromosome 8 Copy Number in Stage I and Stage II Infiltrating Ductal Carcinoma of the Breast," <i>Cancer Genet. Cytogenet.</i> 97:101-105 (September 1997)
	AS	1	Coleman, A.W., <i>et al.</i> , "Mithramycin- and 4'-6-Diamidino-2-Phenylindole (DAPI)-DNA Staining for Fluorescence Microspectrophotometric Measurement of DNA in Nuclei, Plastids, and Virus Particles," <i>J. Histochem. Cytochem.</i> 29:959-968 (August 1981)
✓	AT	1	Craig <i>et al.</i> , "A recombinant adenovirus expressing p27 ^{Kip1} induces cell cycle arrest and loss of cyclin-Cdk activity in human breast cancer cells," <i>Oncogene</i> 14:2283-2289 (May 1997)

EXAMINER

H. Gamilla

DATE CONSIDERED

4/20/02

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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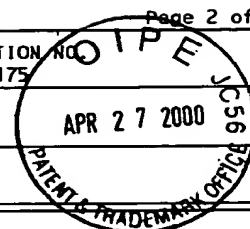
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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	2	El-Habashi, A.H., <i>et al.</i> , "DNA Ploidy and Proliferating Cell Nuclear Antigen Image Analysis of Peritoneal and Pleural Effusions," <i>Acta. Cytol.</i> 41:636-648 (May-June 1997)
↓	AS	2	Fernandes, B.J., <i>et al.</i> , "DNA Content and Estrogen Receptors in Primary Carcinoma of the Breast," <i>Can. J. Surg.</i> 34:349-355 (August 1991)
✓	AT	2	Galand, P. and Degraef, C., "Cyclin/PCNA immunostaining as an alternative to tritiated thymidine pulse labelling for marking S phase cells in paraffin sections from animal and human tissues," <i>Cell Tissue Kinet.</i> 22:383-392 (September 1989)

EXAMINER

J. Gamella

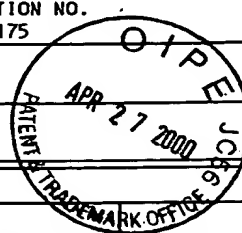
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	3	Gerdes, J., <i>et al.</i> , "Production of a Mouse Monoclonal Antibody Reactive with a Human Nuclear Antigen Associated with Cell Proliferation," <i>Int. J. Cancer</i> 31:13-20 (January 1983)
↓	AS	3	Gross, H.-J., <i>et al.</i> , "Model Study Detecting Breast Cancer Cells in Peripheral Blood Mononuclear Cells at Frequencies as Low as 10 ⁻¹ ," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 92:537-541 (January 1995)
↓	AT	3	Hall, P.A., <i>et al.</i> , "Proliferating Cell Nuclear Antigen (PCNA) Immunolocalization in Paraffin Sections: An Index of Cell Proliferation with Evidence of Deregulated Expression in Some Neoplasms," <i>J. Pathol.</i> 162:285-294 (December 1990)

EXAMINER

G. Garella

DATE CONSIDERED

4/20/02

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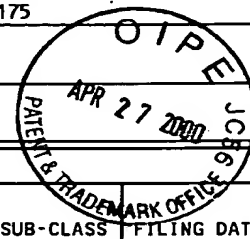
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KA	AR	4	Harvat, B.L., <i>et al.</i> , "The role of p27 ^{Kip1} in Gamma interferon-mediated growth arrest of mammary epithelial cells and related defects in mammary carcinoma cells," <i>Oncogene</i> 14:2111-2122 (May 1997)
↓	AS	4	Heatley, M., <i>et al.</i> , "Cytokeratin intermediate filament expression in benign and malignant breast disease," <i>J. Clin. Pathol.</i> 48:26-32 (January 1995)
✓	AT	4	Katayose, Y., <i>et al.</i> , "Promoting Apoptosis: A Novel Activity Associated with the Cyclin-dependent Kinase Inhibitor p27," <i>Cancer Res.</i> 57:5441-5445 (December 1997)

EXAMINER *G. Gamella*

DATE CONSIDERED *4/20/02*

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	5	Kawada, M. <i>et al.</i> , "Up-regulation of p27 ^{Kip1} Correlates Inversely with Anchorage-independent Growth of Human Cancer Cell Lines," <i>Jpn. J. Cancer Res.</i> 89:110-115 (February 1998)
↓	AS	5	Key, G., <i>et al.</i> , "New Ki-67-Equivalent Murine Monoclonal Antibodies (MIB 1-3) Generated Against Bacterially Expressed Parts of the Ki-67 cDNA Containing Three 62 Base Pair Repetitive Elements Encoding for the Ki-67 Epitope," <i>Lab Invest.</i> 68:629-636 (June 1993)
✓	AT	5	Kirkegaard, L.J. <i>et al.</i> , "Image Cytometric Measurement of Nuclear Proliferation Markers (MIB-1, PCNA) in Astrocytomas," <i>Am. J. Clin. Pathol.</i> 109:69-74 (January 1998)

EXAMINER

H. Gamella

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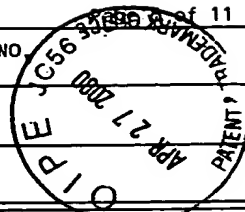
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	6	Lee, A.K.C., <i>et al.</i> , "DNA Ploidy, Proliferation, and Neu-oncogene Protein Overexpression in Breast Carcinoma," <i>Mod. Pathol.</i> 5:61-67 (January 1992)
I	AS	6	Leong, A.S.-Y. and Milios, J., "Is Immunolocalisation of Proliferating Cell Nuclear Antigen (PCNA) in Paraffin Sections a Valid Index of Cell Proliferation?" <i>Appl. Immunohistochem.</i> 1:127-135 (1993)
↓	AT	6	Makris, A., <i>et al.</i> , "Changes in hormone receptors and proliferation markers in tamoxifen treated breast cancer patients and the relationship with response," <i>Breast Cancer Res. Treat.</i> 48:11-20 (March 1998)

EXAMINER

K. Gamella

DATE CONSIDERED

4/20/02

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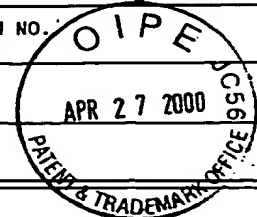
ATTY. DOCKET NO.
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APPLICATION NO.
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<i>KAC</i>	AR	<u>Z</u>	Mathews, M.B., <i>et al.</i> , "Identity of the proliferating cell nuclear antigen and cyclin," <i>Nature</i> 309:374-376 (May 1984)
<i>I</i>	AS	<u>Z</u>	Racila, E., <i>et al.</i> , "Detection and characterization of carcinoma cells in the blood," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 95:4589-4594 (April 1998)
<i>✓</i>	AT	<u>Z</u>	Rao, J.Y., <i>et al.</i> , "Single Cell Multiple Biomarker Analysis in Archival Breast Fine-Needle Aspiration Specimens: Quantitative Fluorescence Image Analysis of DNA Content, p53, and G-actin as Breast Cancer Biomarkers," <i>Cancer Epidemiology, Biomarkers & Prevention</i> 7:1027-1033 (November 1998)

EXAMINER *J. Ganelle*

DATE CONSIDERED *4/20/02*

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U.S. PATENT DOCUMENTS

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAL	AR	8	Sasano, H., <i>et al.</i> , "Immunolocalization of Cyclins D and E and Cyclin Dependent Kinase (cdk) 2 and 4 in Human Breast Carcinoma," <i>Anticancer Res.</i> 17:3685-3690 (September-October 1997)
I	AS	8	Scambia, G., <i>et al.</i> , "Multiple Tumour Marker Assays in Advanced Cervical Cancer: Relationship to Chemotherapy Response and Clinical Outcome," <i>Eur. J. Cancer</i> 32A:259-263 (February 1996)
✓	AT	8	Shackney, S.E., <i>et al.</i> , "Aneuploidy in Breast Cancer: A Fluorescence In Situ Hybridization Study," <i>Cytometry</i> 22:282-291 (December 1995)

EXAMINER

K. G. Canella

DATE CONSIDERED

4/20/02

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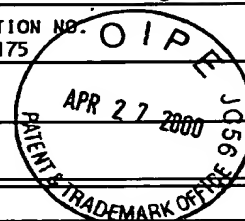
KAC	AR	2	Siitonen, S.M., <i>et al.</i> , "Proliferating Cell Nuclear Antigen Immunohistochemistry Using Monoclonal Antibody 19A2 and a New Antigen Retrieval Technique Has Prognostic Impact in Archival Paraffin-Embedded Node-Negative Breast Cancer," <i>Am. J. Pathol.</i> 142:1081-1089 (April 1993)
↓	AS	2	Simpson, S.J., <i>et al.</i> , "Detection of tumor cells in the bone marrow, peripheral blood, and apheresis products of breast cancer patients using flow cytometry," <i>Exp. Hematol.</i> 23:1062-1068 (September 1995)
↓	AT	2	Tan, P., <i>et al.</i> , "The Cell Cycle Inhibitor p27 Is an Independent Prognostic Marker in Small (T _{1a,b}) Invasive Breast Carcinomas," <i>Cancer Res.</i> 57:1259-1263 (April 1997)

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DATE CONSIDERED 4/20/02

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1887.0020001/RWE/KKV	APPLICATION NO. 09/430,175
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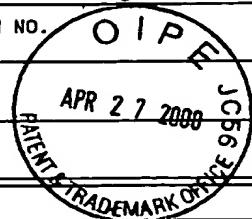
OTHER (Including Author, Title, Date, Pertinent Pages, etc.)			
KAC	AR	10	Tsihlias, J., <i>et al.</i> , "Loss of Cyclin-dependent Kinase Inhibitor p27 ^{Kip1} Is a Novel Prognostic Factor in Localized Human Prostate Adenocarcinoma," <i>Cancer Res.</i> 58:542-548 (February 1998)
↓	AS	10	van Oijen, M.G.C.T., <i>et al.</i> , "Positivity of the Proliferation Marker Ki-67 in Noncycling Cells," <i>Am. J. Clin. Pathol.</i> 110:24-31 (July 1998)
↓	AT	10	Vielh, P. <i>et al.</i> , "Ki67 Index and S-Phase Fraction in Human Breast Carcinomas," <i>Am. J. Clin. Pathol.</i> 94:681-686 (December 1990)

EXAMINER	<i>H. Gannella</i>	DATE CONSIDERED	4/28/02
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	11	Wingren, S., <i>et al.</i> , "Flow cytometric analysis of S-phase fraction in breast carcinomas using gating on cells containing cytokeratin," <i>Br. J. Cancer</i> 69:546-549 (March 1994)
KAC	AS	11	Zhu, K., <i>et al.</i> , "Estrogen Receptor Status of Breast Cancer: A Marker of Different Stages of Tumor or Different Entities of the Disease?" <i>Med. Hypotheses</i> 49:69-75 (July 1997)
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K. Gancella

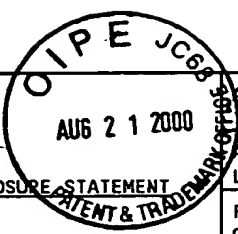
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AUG 21 2000

ATTY. DOCKET NO.
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FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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KAC	AO1	WO 97/38313	10/16/1997	WIPO			Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

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KAC	AT	11	Ben-Hur, H., <i>et al.</i> , "Menopause Is Associated With a Significant Increase in Blood Monocyte Number and a Relative Decrease in the Expression of Estrogen Receptors in Human Peripheral Monocytes," <i>Am. J. Reproductive Immunol.</i> 34:363-369 (1995).

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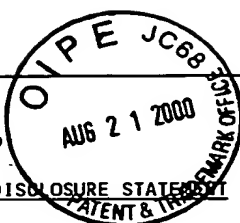
J. Gamella

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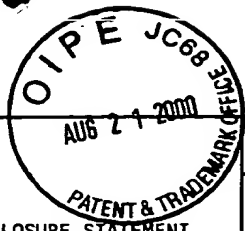
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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAL	AR	12	Berd, D., and Mastrangelo, M.J., "Effect of Low Dose Cyclophosphamide on the Immune System of Cancer Patients: Depletion of CD4+, 2H4+ Suppressor T-Cells," <i>Cancer Res.</i> 48:1671-1675 (March 1988).
KAL	AS	12	Bischoff, F.Z., <i>et al.</i> , "Prenatal diagnosis with use of fetal cells isolated from maternal blood: Five-color fluorescent in situ hybridization analysis on flow-sorted cells for chromosomes X, Y, 13, 18, and 21," <i>Am. J. Obstet. Gynecol.</i> 179:203-209 (1998).
KAL	AT	12	Clatch, R.J., and Foreman, J.R., "Five-color Immunotphenotyping Plus DNA Content Analysis by Laser Scanning Cytometry," <i>Cytometry</i> 34:36-38 (1998).

EXAMINER *H. Canella*DATE CONSIDERED *4/20/02*

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.



FORM PTO-1449

FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.
1887.0020001APPLICATION NO.
09/430,175APPLICANT
Lesko *et al.*FILING DATE
October 29, 1999GROUP
1648

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	13	Dick, A.D., <i>et al.</i> , "Flow cytometric identification of a minority population of MHC class II positive cells in the normal rat retina distinct from CD45 ^{low} CD11b/c'CD4 ^{low} parenchymal microglia," <i>Br. J. Ophthalmol.</i> 79:834-840 (1995).
KAC	AS	13	Douglas, R.S., <i>et al.</i> , "Novel Approach for Simultaneous Evaluation of Cell Phenotype, Apoptosis, and Cell Cycle Using Multiparameter Flow Cytometry," <i>Cytometry</i> 32:57-65 (1998).
KAC	AT	13	Keller, R.K., <i>et al.</i> , "Density Gradient Centrifugation of Colonic Fluid After Segmental Lavage: A Method of Purification of Exfoliative Epithelial Colonic Cells for Cytological Interpretation and Image Cytometry in Patients With Long-Standing Ulcerative Colitis," <i>Am. J. Gastroenterology</i> 94:404-409 (1999).

EXAMINER

R. Canella

DATE CONSIDERED

4/20/02

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAL	AR	14	Kroegel, C., <i>et al.</i> , "Blood and bronchoalveolar eosinophils in allergic subjects after segmental antigen challenge: Surface phenotype, density heterogeneity, and prostanoid production," <i>J. Allergy Clin. Immunol.</i> 93:725-734 (1994).
KAL	AS	14	Morikawa, K., <i>et al.</i> , "Induction of CD5 antigen on human CD5- B cells by stimulation with <i>Staphylococcus aureus</i> Cowan strain 1," <i>Int'l. Immunol.</i> 5:809-816 (1993).
KAL	AT	14	Roussev, R.G., <i>et al.</i> , "Phenotypic characterization of normal human placental mononuclear cells," <i>J. Repro. Immunol.</i> 25:15-29 (1993).

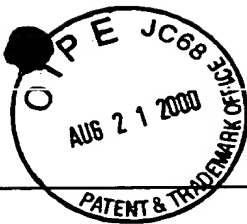
EXAMINER

J. Garella

DATE CONSIDERED

4/20/82

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<i>KAC</i>	AR	<u>15</u>	Woitak, R.P., <i>et al.</i> , "CD30 Induction and Cytokine Profiles in Hepatitis C Virus Core-Specific Peripheral Blood T Lymphocytes," <i>J. Immunol.</i> 159:1012-1018 (1997).
	AS	<u>15</u>	
	AT	<u>15</u>	

EXAMINER

H. Gamella

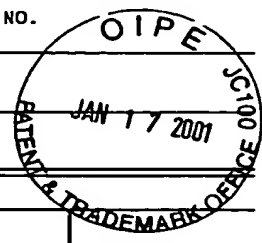
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FORM PTO-1449 SECOND SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1887.0020001/RWE/KKV	APPLICATION NO. 09/430,175
	APPLICANT Lesko et al.	
	FILING DATE October 29, 1999	GROUP 1648



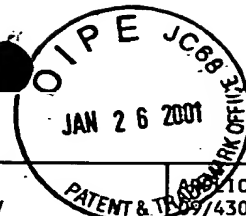
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KAC	AD1	5,633,945	05/27/97	Kamentsky	328	129	10/05/94
KAC	AE1	6,169,816	01/02/01	Ravkin	382	128	05/04/98
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

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EXAMINER <i>G. Gamelle</i>	DATE CONSIDERED <i>4/20/02</i>
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FORM PTO-1449

THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

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1887.0020001/RWE/KKVAPPLICATION NO.
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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR		
KAC	AS15		Galbraith, W. et al., "Imaging Cytometry by Multiparameter Fluorescence," <i>Cytometry</i> 12: 579-596 (1991) (publisher: Wiley-Liss, Inc.).
KAC	AT15		Waggoner, A. et al., "Multiparameter Fluorescence Imaging Microscopy: Reagents and Instruments," <i>Human Pathology</i> 27(5): 494-502 (May 1996) (publisher: W.B. Saunders Company).

EXAMINER *H. Gamella*DATE CONSIDERED *9/20/02*

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FORM PTO-1449 THIRD SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1887.0020001/RWE	APPLICATION NO. 09/430,175
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	16	Chen, K.Y. <i>et al.</i> , "Detection of Circulating Cancer Cells from Prostate Cancer Patients' Blood," <i>The First China Taiwan Cancer Conference</i> , Haerbing, People's Republic of China (January 8-12, 1999)
↓	AS	16	Eisenberger, M.A. <i>et al.</i> , "Detection and Characterization of Circulating Prostate Cancer Cells in the Blood of Patients with Prostate Cancer," from <i>Annual Meeting for the Society of Chinese Bioscientists in America</i> , Toronto (July 1997)
↓	AT	16	Polascik, T.J. <i>et al.</i> , "Harvest of Intact Prostate Cancer Cells from Blood: Further Characterization of a New Assay," <i>J. Urology</i> 159:Supplement (May 31, 1998), from the <i>Annual Meeting of the American Urological Association</i> , San Diego, California, May 30-June 4, 1998

EXAMINER <i>H. Gamelle</i>	DATE CONSIDERED <i>4/20/82</i>
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	17	Polascik, T.J. et al., "Influence of Sextant Prostate Needle Biopsy or Surgery on the Detection and Harvest of Intact Circulating Prostate Cancer Cells," J. Urology 162:749-752, American Urological Association, Inc. (September 1999)
I	AS	17	Ts'o, P.O.P., "Biomarkers Expression and Characterization of Prostate Cancer Circulating Cells," from Scientific Poster Reproductions of CaP CURE: Sixth Annual Scientific Retreat, Lake Tahoe, Nevada, October 14-17, 1999, Association for the Cure of Cancer of the Prostate, Santa Monica, California
✓	AT	17	Wang, Z.P. et al., "Detection incidence of circulating cancer cells from prostate cancer patients' blood," Abstract No. 4708, from the American Association of Cancer Research (AACR) Annual Meeting, Philadelphia, Pennsylvania (April 10-14, 1999)

EXAMINER H. Gamelle	DATE CONSIDERED 4/20/02
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

KAC	AR	18	Wang, Z.-P. <i>et al.</i> , "Identification and Characterization of Circulating Prostate Carcinoma Cells," <i>Cancer</i> 88:2787-2795, American Cancer Society (June 15, 2000)
I	AS	18	Wang, Z.P. <i>et al.</i> , "Indications of living circulating prostatic cancer cells in the prostatic cancer patients' blood," from <i>International Symposium on Biology of Prostate Growth</i> , National Institutes of Health, Bethesda, Maryland (March 15-18, 1998)
✓	AT	18	Wang, Z.-P. <i>et al.</i> , "Intravascular growth may occur in the formation of a metastatic tumor," <i>Conference on New Research Approaches in the Prevention and Cure of Prostate Cancer</i> , Indian Wells, California, American Association for Cancer Research (December 2-6, 1998)

EXAMINER

K. Gamella

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4/20/02

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